Department of Veterans Affairs

Northern California Health Care System

Research Services

Research and Development Committee

Standard Operating Procedures (SOP)

(20th Version)

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I. POLICY

It is VHA policy that each VA medical facility conducting research must establish an R&D Committee or enter into a written agreement with another VA medical facility to use that institution's R&D Committee. All VA research must be approved by the R&D Committee and cannot be initiated until the Associate Chief of Staff for Research & Development (ACOS/R&D) has notified the Principal Investigator (PI) in writing that all approvals are in place. Once approved, VA is responsible for all aspects of the research, including oversight by the R&D Committee, appropriate subcommittees, and when applicable, VHA Office of Research and Development and VHA Office of Research Oversight.

II.INTRODUCTION

A. This Standard Operating Procedure (SOP) is a local implementation of VHA Directive 1200.01 and establishes the responsibilities and operations of the Research and Development Committee (R&DC) at VA Northern California Health Healthcare System (VANCHCS). This committee, which reports to the Medical Executive Committee (MEC) at VANCHCS, chaired by the Chief-of-Staff (COS), is responsible for advising and assisting the Medical Center Director in providing oversight, planning, and execution of the local research program; and assisting the Medical Center Director in maintaining high standards throughout the R&D Program. The R&DC provides advice and guidance to the facility leadership and specifically to the Director in regard to research oversight, budgeting and administrative oversight. In addition, the R&DC has ultimate responsibility for approving all research conducted by VANCHCS.

B. Guidance from the VHA Directive1200.01 permits the R&DC to assign scientific review and some administrative responsibilities, including oversight and compliance issues, to appropriate subcommittees and individuals. This enables the R&DC to prioritize their deliberations around broad areas of program development, risk management, and quality performance activities.

C. This SOP and attached procedures apply to the day-to-day operations of the R&DC of the VANCHCS and serves as a reference document for the R&DC members. This Manual details the procedures outlining the functions of the R&DC in its oversight of the research program, in overseeing the functions of its internal subcommittees, including the Institutional Review Board (IRB) and the Subcommittee for Research Safety and Security (SRS), as well as other research-related committees including the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biological Safety Committee (IBC), and, in some cases, the review of research proposals. Further, the R&D committee is also responsible for oversight of research conducted at VANCHCS that is overseen by the VA Central IRB (CIRB) or by other IRBs listed on the facility Federal wide Assurance.

D. The R&DC is responsible for ensuring that all research is conducted in a manner that protects the safety, rights, welfare and other interests of human and animal subjects, as well as VA employees, WOCs and volunteers engaged in that research under the applicable statutes of the Common Rule (38 CFR 16), the Federal Policy for the Protection of Human Subjects (45 CFR 46), the regulations of the Food and Drug Administration (FDA) (21 CFR 50, 54, 56, 312, and 812), VHA 1200.01 and the State of California Health and Safety Code. The R&DC will also conform to the policy guidance of the Office for Human Research Protections (OHRP) and the Office of Research Oversight (ORO).

III.SCOPE

A. The VANCHCS Director has established and authorized the R&DC to oversee research that is conducted under the authority of the VANCHCS.

B. The R&DC is responsible, through the Chief of Staff (COS), for advising and assisting the Medical Center Director in providing oversight, planning, and execution of the local research program; and for maintaining high standards throughout the R&D Program. Those standards include: (i) ensuring the scientific and ethical quality of VA research projects; (ii) the protection of human subjects in research; (iii) the safety of personnel engaged in research; (iv) the welfare of laboratory animals; (v) the security of VA data; and (vi) the security of VA research laboratories. Focus is directed on oversight responsibilities of establishing and maintaining policies and procedures, SOPs, Standard Operating Manuals (SOM)s, processes, and ensuring that deliberations are based around program development, proper review of research, budgetary considerations, risk management and Quality Improvement (QI) activities. (Refer to Attachment Research and Development Committee Oversight Procedures)

C. The R&DC is assisted by the Associate Chief of Staff for Research Service (ACOS/R) and the Administrative Officer for Research Service (AO/R) in carrying out its duties.

IV. RESPONSIBILITIES OF THE MEDICAL CENTER DIRECTOR

A. The Director serves as the Institutional Official responsible for all aspects of the research program and meeting the requirements outlined in VHA Directive 1200.01. This includes, but is not limited to: human subjects protection, animal welfare care and use, privacy and security of VA data, and biosafety; ensuring that research in which the facility is engaged is approved by the R&DC and the appropriate R&DC subcommittees; ensuring there are adequate resources and administrative support, including personnel, space, equipment, and training, for the R&DC and its subcommittees to fulfill their responsibilities; ensuring appropriate education and training for members of the R&DC, the research administration staff, and other staff involved in research; and appointing in writing members of the R&DC and its subcommittees. These processes will be outlined in this SOP; it's attachments or will reference to Research Service SOP and facility-wide Policies & Procedures(P&P).

B. The Director must also ensure that open channels of communication are maintained between the R&DC, committee members, Chairs, research investigators, staff, and facility management; and that the R&DC is provided with sufficient meeting space and staff to support its substantial review and confidential record keeping responsibilities.

C. When the VA Central IRB (VA CIRB) is the IRB of Record for a study, the Director is also responsible for signing and adhering to the Memorandum of Understanding (MOU) between VA Central Office (VACO) and VANCHCS. The Director is the delegating authority for commenting and responding to VA CIRB review in response to initial review considerations, whether VANCHCS chooses or declines to participate in a study and serving as liaison between VANCHCS as well as the Local Site Investigator (LSI) with VA CIRB. The Research Service/Human Resources Protection Program (HRPP) will ensure the completion of the component reviews/Subcommittee of Record Review for the R&DC. Similarly, when the IRB of any other institution serves as the IRB of Record for a study, the Director is responsible for signing and adhering to the MOU between the other institution and VANCHCS.

D. Suspending or terminating research that has been approved by the R&D Committee when concerns are raised and substantiated about the conduct of the research (refer to VHA Handbook 1058.02, Research Misconduct, dated February 7, 2014, and VHA Handbook 1058.04, Debarments and Suspensions Based on Research Impropriety in VA Research, dated April 15, 2013).

V. RESPONSIBILITIES OF THE ACOS FOR RESEARCH SERVICE (ACOS/R)

A. The ACOS/R is the delegated authority for management of the R&D program (per guidance from VHA Directive 1200.01) and is responsible for administering the support functions for the R&DC. He/she serves as an *ex officio* member (without vote) and Executive Secretary of the R&DC.

B. The ACOS/R is responsible for reviewing and evaluating actions and reports of the R&DC and its subcommittees to help ensure communication between committees and to ensure continuous quality improvement (QI) within research service. The ACOS/R maintains communication with the R&DC in the following ways:

i. Meets regularly with the R&D leadership staff and R&DC Chair regarding the program.

ii. Reviews minutes of the R&DC and other subcommittees and provides feedback to their Chairs.

iii. Attends R&DC, Institutional Review Board (IRB) and Subcommittee for Research Safety (SRS) meetings, *ad hoc* meetings, and any subcommittee meetings as an *ex-officio* member.

C. The ACOS/R is responsible for notifying the investigator when a research project can be initiated. This notification occurs only after the research project has been approved by applicable subcommittees and the R&DC. Such notification shall be in writing and shall detail the approval period as determined by the subcommittee/committee of record.

D. Ensuring that all minutes of the R&DC are routed through the COS for the Director's signature and presented to the Executive Management Board which includes the Medical Center Director, Associate Directors, COS, Associate Director for Patient Care Services, and other members of facility leadership.

E. Assisting in tracking open items and actions for the R&DC and Director.

VI. RESPONSIBILITIES OF THE R&D COMMITTEE

A. The R&DC is responsible for planning and developing broad objectives for the research program to support the VA mission and institution's HRPP Program and determining the extent to which the research program has met its objectives. The R&DC ensures the effective operation of the research program through oversight of the R&DC subcommittees and other research-related committees and the facility's research portfolio. The R&DC Annual Review, completion of the ORO checklist for R&DC, and the Quality Improvement process will be used to evaluate this function. Based on the Committee's oversight and evaluation of the research program, the R&DC makes appropriate recommendations to the Medical Center Director. (Refer to Attachment Research and Development Committee Oversight Procedures)

B. The R&DC assures a high-quality research program, including approvals of all MOUs, affiliation agreements, service agreements, FWA review, lease agreements, policies, procedures, manuals and/or SOPs of all subcommittees. Any R&DC approved MOU regarding the HRPP will be forwarded to the appropriate VACO Office of Research and Development (ORD), and ORO offices.

C. Reviewing research proposals and approving the research, requiring modifications to obtain approval, or disapproving the research. The R&DC will review all subcommittee written approval letters, signed by an authorized voting member of that subcommittee and will review the R&DC Checklist or equivalent that verifies all required component reviews have been completed.

D. Ensuring that all research in which the facility is engaged is consistent with the VA mission and complies with all applicable statutory and regulatory requirements.

E. Establishing appropriate subcommittees to review and oversee human subjects research, animal research, and safety and security reviews. For protocols not meeting criteria for assignment to any subcommittee according to local SOPs, the R&D Committee is the review and approving committee of record.

F. Ensuring Information System Security Officer (ISSO) and Privacy Officer (PO) review is complete before a study is given final approval. NOTE: The R&D Committee can approve contingent on ISSO and PO review.

G. Determining whether the facility should participate in a study and ensuring that the appropriate Institutional Review Board (IRB) agreements are in place as required by VHA Directive 1200.05, Requirements for the Protection of Human Subjects in Research, dated January 7, 2019, and VHA Handbook 1058.03, Assurance of Protection of Human Subjects in Research, dated November 21, 2014, prior to using the external IRB when a study is reviewed by an IRB of another Federal agency (for example, the National Cancer Institute Central IRB) or a non-VA IRB serving as the multi-site IRB for a study. Note: An external IRB is an IRB of another Federal agency or another non-VA institution's IRB. Directive 1200.01 clarifies that VACO IRB or another VA facility's internal IRB is not considered to be an external IRB (see also VHA Directive 1200.05).

H. Establishing procedures to ensure that all research in which the facility is to be engaged has been reviewed and approved for high scientific quality, the protection of human subjects and research staff, the welfare of animal subjects, the safety of all involved in research, the security of research laboratories, and the security of VA Data and sensitive information.

I. Establishing a local R&D Conflict of Interest Committee to ensure that potential financial conflicts of interest are reported, reviewed, and managed in accordance with government ethics rules and regulations and VA ethics policies. To facilitate operations, the R&D Conflict of Interest Committee will be combined with the R&D Committee; the R&D Committee will perform the functions (see below) of the R&D Conflict of Interest Committee.

J. The R&DC ensures committee members meet minimal training requirements as tracked through Research Service and reported at least annually to R&DC.

K. The R&DC ensures implementation of needed improvements and follow-up on actions, including review of Research Compliance Officer (RCO) and QI reports for appropriate actions.

L. Reviews the utilization of resources: Evaluates and makes recommendations on HRPP, Research Service Office budgets, PI budget issues, status of non-profit or General Post Funds (GPF). The R&DC may consider

factors such as personnel, materials, supplies, education and training, space, capital equipment including related upkeep and repairs. Reviews and approves requests for expenditures from Research General Post Funds. Ensures budget reports for the Research Service and PI accounts are reported at least annually or at the request of the R&DC as needed to ensure appropriate research budget oversight.

M. The R&DC has the authority to suspend a research study or require remedial or restrictive action regarding a principal investigator. The R&DC may rely on a variety of information sources such as quality assurance activities, reports to the committee by the ACOS/R, AO/R, or other research staff members, subcommittee reports, facility reports or activities, RCO reports and other appropriate sources.

N. Ensures compliance with established procedures to maintain the integrity of information reported with the VANCHCS FWA. This includes ensuring reporting of the ACOS/R regular review of the FWA and monitoring compliance and updates reported by ACOS/R and/or RCO.

O. Research space allocation and renovation is addressed as part of the facility and VISN-wide Space Committee. A member of the Research Service leadership will attend the facility wide meetings and act as a conduit for space issues to and from the R&DC and Research Service. This representative will update the R&DC at least annually or as issues with research space and allocation arise. The R&DC can direct and advise the ACOS/R and the AO/R in utilization of space assigned to the Research Service by the facility.

VII. RESPONSIBILITIES OF THE RESEARCH AND DEVELOPMENT CONFLICT OF INTEREST COMMITTEE (Combined with the R&D Committee)

Note: Per April 19, 2019 update from the Deputy Under Secretary for Health (DUSH) for Discovery, Education, and Affiliate Networks, implementation of Conflict of Interest Review by the Research and Development Conflict of Interest Committee will be delayed. The below implementation of Conflict of Interest Review by the Research and Development Conflict of Interest Committee will occur when notification to do so is received from the Office of Research Protections, Policy, and Education and/or the DUSH for Discovery, Education and Affiliate Networks. All other provisions of this SOP (except as indicated) will be implemented at the time of signing by the R&DC Chair and the ACOS/Research. The R&D Conflict of Interest Committee is responsible for reviewing completed, signed and dated OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement submitted by VA investigators. This committee will ensure that any potential financial conflicts of interest are reported, reviewed, and managed in accordance with government ethics rules and regulations and VA ethics policies. This committee will meet on a regular schedule that meets the needs of the research program. Any positive responses on OGE Form 450 Alternative-VA that could involve criminal conflict of interest or Standards of Conduct will be referred to the Designated Agency Ethics Official (DAEO). NOTE: The DAEO, the Principal Deputy General Counsel, the Alternate DAEO, and the OGC Ethics Specialty Team address issues involving the application of criminal conflict of interest laws (18 U.S.C. Chapter 11) and the Standards of Conduct for Executive Branch Employees (5 CFR Part 2635). The DAEO, the Alternate DAEO and the Ethics Specialty Team are the only sources of authoritative advice on criminal conflicts of interest and the legal questions relating to Standards of Conduct. These Deputy Ethics Officials can be contacted at governmentethics@va.gov. Full disclosure of all the relevant facts to the designated agency ethics officials and good faith reliance on that advice provides the employee with meaningful protection from criminal or administrative sanctions. The imposition of criminal sanctions ultimately rests with the Department of Justice after receiving the matter from the Inspector General.

VIII. RESPONSIBILITIES OF INFORMATION SYSTEM SECURITY OFFICER

The ISSO is responsible for ensuring that the proposed research complies with information security requirements for VA sensitive information (see VA Handbook 6500, Managing Information Security Risk: VA Information Security Program, dated September 20, 2012).

IX. RESPONSIBILITIES OF PRIVACY OFFICER

The PO is responsible for ensuring that the proposed research complies with VA Privacy requirements and the HIPAA Authorization contains all required elements (see VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016).

X. RESPONSIBILITIES OF VA INVESTIGATORS

Each VA investigator is responsible for

A. Developing a research plan that is scientifically valid; minimizes risk to human and animal subjects used in research and to research personnel; and contains a sufficient description of the research, including all procedures, and the plan for statistical analysis, to allow the R&D Committee and its subcommittees and other research-related committees to fully review the research project. The research protocol must differentiate research procedures from those clinically indicated procedures performed on research subjects as part of standard clinical care.
B. Obtaining approval by all appropriate non-research entities and R&D Committee subcommittees, and other applicable research committees, and initiating a research project only after receiving written notification of approval from the ACOS/R&D.
C. Submitting a completed, signed, and dated OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement (https:/www.research.va.gov/programs/tech_transfer/model agreements/conflict_of_interest.pdf), for review by the R&D Conflict of Interest Committee prior to:
    - Initial review of a study protocol in which the employee is listed as an Investigator;
    - Continuing review of a study protocol in which the employee is listed as an Investigator;
    - The employee being added as an Investigator to a study protocol; and
    - When a change in relevant information requires that the Investigator change an answer in Section 1 of an earlier-filed OGE Form 450 Alternative – VA, to "yes" or that changes the reason for a "yes" answer.
D. Submitting and implementing plans for data use, storage, and security to the PO and ISSO that are consistent with VHA Directive 1605.01, VA HA Directive 6500, implementing handbooks, and other legal requirements.
E. Preparing and submitting information, at least annually or as otherwise required, on all research projects to the appropriate R&D Committee subcommittee or the R&D Committee for continuing review. For research projects exempted from continuing review by the 2018 requirements of the Common Rule, these materials will include at a minimum a) a brief summary of research findings, b) a list of presentations, and c) a list of publications, and d) indication of whether the PI wishes to continue the protocol into the next year.
F. Ensuring that research proposals support the mission of VHA and enhance the quality of health care for Veterans.

XI. R&D COMMMITTEE MEMBERSHIP

Members of the R&DC are appointed by the Medical Center Director after nomination through the R&DC through majority vote and must reflect the types and amount of research being conducted at the facility. Nominations for membership may be from current R&DC members, subcommittee members, and facility staff. All members of the R&D Committee must hold VA appointments (permanent, term, IPA, or WOC). **All members will agree and adhere to a policy of confidentiality, whereby the member is forbidden from disclosing to the outside community, the nature of the discourse during the meeting, unless specifically asked to communicate that issue by the ACOS/R, the R&DC Chair, the Medical Center Director or the Chief of Staff.**

A. Membership of the R&DC

i. The R&DC must consist of at least five voting members and required *ex officio* members.

ii. Whenever possible, one member needs to have expertise in biostatistics and research design.

iii. The membership needs to have diverse backgrounds with consideration as to race, gender, ethnicity, and expertise.

B. Voting members of the R&DC must include, but are not limited to:

i. At least two members from the VA facility's staff who have major patient care or management responsibilities.

ii. At least two members who are VA investigators actively engaged in major R&D programs or who can provide R&D expertise.

iii. The VANCHCS Research Pharmacist or a pharmacy representative, and a representative of each of the standing subcommittees.

iv. A voting member may fill more than one criterion for required membership, for example, the member may have both major patient care or management responsibilities and be actively engaged in major R&D programs.

C. Alternate members must be appointed by the facility Director. The roster must identify the primary member(s) for whom each alternate member may substitute. The alternate member's qualifications must be comparable to those of the primary member(s) to be replaced. The alternate member can only vote in the absence of the primary members he/she is designated as an alternate.

i. The R&DC may require attendance by R&DC subcommittee members, but subcommittee members who are not also members of the R&DC may not contribute to a quorum or deliberate or vote with the R&DC.

D. *Ex-Officio* Members

i. *Ex officio* (non-voting) members of the VANCHCS R&DC include the Medical Center Director (Associate Directors as alternate to the Medical Center Director), the COS/Deputy Chief of Staff, the ACOS/R, the AO/R, IRB Chairperson, SRS Chairperson, Institutional Animal Care and Use Committee (IACUC) Representative, Institutional Biosafety Committee (IBC) Representative, HRPP Manager, The facility Privacy Officer and Information System Security Officer and the Executive Director of the affiliated nonprofit when appropriate.

E. **Consultants.** Others may be invited to assist the R&DC because of their competence in special areas in the review of issues requiring expertise beyond, or in addition to, that available on the Committee. These individuals may not contribute to a quorum, deliberate or vote with the Committee.

F. **Research Compliance Officer**. The Research Compliance Officer (RCO) may serve as a non-voting consultant, as needed to the facility's R&D Committee.

G. **Terms of Members**

i. Voting members and *ex-officio* members not identified above, are appointed by the Medical Center Director in writing and serve terms of up to 3 years with a possibility for extension. Members may be reappointed without any lapse in time if it is deemed in the Committee's best interest.

ii. The terms of members must be staggered to provide continuity in membership.

iii. Appointment letters must be signed by the Director and specify:

a. The term of the appointment.

b. Whether the basis is regular, *ex officio*, or alternate. (Members whose position in VANCHCS identified above as *ex officio* does not need an appointment letter)

c. The voting status of the appointment

H. **Election of Chairperson**. Committee members, exclusive of *ex officio* non-voting members, must elect a Chairperson every 1 or **2 years**.

i. The Chairperson must be approved and officially appointed, in writing, by the Medical Center Director for a term of 1 or 2 years.

ii. The Chairperson may be reappointed without any lapse in time.

iii. The Chairperson must not simultaneously chair a sub-Committee of the R&DC.

iv. The committee may also appoint a Chair Pro Tempore or Vice Chair to serve when the Chairperson is absent or has a conflict of interest that requires recusal.

I. **Members Expectation**

i. All members of the R&DC must fulfill the educational requirements specified by VANCHCS R&D Service SOP. Also, every 3 years the Chair and voting members of the R&DC Committee are required to complete two modules from ORD and Collaborative Institutional Training Initiative (CITI) on ethical principles of human research protection. Approved courses are listed on ORD's website at: https://www.research.va.gov/programs/pridePRIDE/training/options.cfm. Committee member who are not up-to-date with research training requirements will not vote or count towards quorum until training has been completed.

ii. New members, prior to their appointment, must complete educational requirements as described above and attend at least one meeting as guest to observe the meeting.

iii. All members must maintain professionalism at all times and participate in respectful discussions.

iv. Voting members must attend at least 75% of the regularly scheduled meetings for the calendar year. Voting members who do not meet this requirement will be removed from the R&DC.

v. Voting members must notify the R&D Coordinator if attendance at a meeting is not possible.

vi. Voting members must notify the R&DC if the member will be on sabbatical or other long-term leave (greater than 3 months). Members on sabbatical or long-term leave will be temporarily removed from

the R&DC and re-instated upon return.

vii. The R&DC will annually evaluate itself to ensure that the membership fulfills all time sensitive requirements of the VANCHCS.

J. Policy regarding Guests:

i. Guests may be allowed to attend a meeting or part of a meeting given that the guest receives, prior to the meeting, an invitation from the R&DC Chair to attend; the R&DC Chair may delegate this responsibility to the ACOS/R&D.

ii. All guests will be required to sign a Confidentiality agreement and agree not to disclose the information gathered by them during the meeting, to any outside entity.

iii. This policy will hold both for guests attending in person or on the phone. If needed**, the R&DC can initiate action against the concerned individuals if they are found to violate the trust of the** Committee.

XII. R&D COMMITTEE OPERATIONS

A. The R&DC must meet on a regular schedule as needed to meet the demands of the research program. Members participating either directly (in room) or through teleconferencing or videoconferencing are to receive agendas and other pertinent material at least 48 hours prior to the meeting so as to enable them to participate actively, knowledgably and equally in all discussions.

B. The R&DC can hold *ad hoc* meetings, with a quorum, in response to emergent issues.

C. All official business must be conducted at a convened meeting with a quorum present except for when a designated review procedure is permitted (see below). No voting item at the R&DC can be voted on by e-mail or by proxy.

Minutes for each meeting must be documented and disseminated to facility leadership through the ACOS/R for review and appropriate action. Dissemination to facility leadership will be accomplished by presenting these minutes to the Executive Management Board (through the COS and Director) which includes as members the Director, Associate Directors, COS, Associate Director for Patient Care Services, and other members of facility leadership.

i. The R&DC minutes are completed by the R&DC Coordinator or designated research staff in the absence of the R&DC Coordinator. Minutes shall include items of the key business conducted at the R&DC and include a summary of any discussions, deliberations, modifications required, all actions taken by the convened R&DC and the votes underlying those actions. The minutes must briefly summarize deliberations of oversight functions to include items needing further review and action and approval of all VA research. Minutes will include, but are not limited to:

a. Time and date of the convened meeting.

b. Attendance and absence by name of all voting and non-voting members, including ex officio members. If an alternate is present, the minutes must state the name of the voting member and indicate who the alternate member is replacing.

c. The presence of a quorum.

d. Approval of prior meeting minutes.

e. All items of business or information brought before the R&DC.

i) The type of action (approval/disapproval/favorable opinion/negative opinion)

ii) The vote on the action, including the number voting for, against, and abstaining. In addition, any recused member from the vote **must be named**, and whether the person was present during the discussion. NOTE: If the member is recused, the member must not be present for the vote, and may not be counted toward the quorum.

1) Actions which require a vote will be categorized as the number who voted "for," "against," or "abstained," and will indicate "recused," and "excused" for those members not voting. Any individuals who are recused from a vote will be noted by name, and notation will be made on whether or not the person was present during the discussion. When a member is recused, they must not be present for the vote and may not be counted toward a quorum.

f. Summary of controversial issues and their resolutions.

g. Date, time and location of the next meeting.

h. Recurring processes and calendared reviews are outlined on the R&DC Agenda.

D. SOPs or other written procedures must be maintained for al recurring procedures. These processes include, but are not limited to, communication with the facility Medical Director, the COS, investigators, and committees and subcommittees.

E. The R&D Committee reviews all research related committees (such as the affiliate IACUC and IBC, which serve as the IACUC and IBC for VANCHCS through MOU) and subcommittees at least annually in part by: reviewing the minutes of each subcommittee that reviews VA research protocols; by close communication with the subcommittees; and through Quality Assurance and Quality Improvement activities. When the facility uses an IRB other than its own internal IRB, such as, but not limited to, the VACO IRB (CIRB), the IRB of another Federal agency, or a non-VA academic institution's IRB, the role of the R&D Committee is to review and evaluate facility specific aspects of these relationships, rather than the committee itself, to ensure that the obligations as detailed in the MOU are being met. Review of an external committee would include evaluation of the number of projects handled by the committee, communication between entities, changes in MOU or other agreements, change in processes, or challenges. A summary of these reviews and evaluations must be sent to the facility Medical Center Director annually.

XIII. R&D COMMITEE RESPONSIBILITIES FOR THE REVIEW OF RESEARCH

A. The R&DC is responsible for establishing policy to ensure that all research in which the facility is to be engaged has been reviewed and approved for the ethical use of human subjects, animals, and biohazards. No study can be initiated until the ACOS/R, acting upon the R&DC approval, notifies the investigator in writing that the study has been approved by the R&DC, as per the following conditions -

i. All research activities conducted at VANCHCS will be reviewed and approved by applicable subcommittees, including all initial reviews, reviews of amendments, adverse events, QI issues and closures, and if required, continuing reviews. Of the above, all initial reviews will necessarily require approval by the R&D committee prior to initiation. Amendments, adverse events, and closures do not require review by the R&DC unless deemed necessary by the subcommittee of record or the R&DC Chair. In addition, continuing review will not require review by the R&DC

unless the approval had lapsed.

ii. For protocols not meeting criteria for assignment to any subcommittee, the R&DC review will occur as described below under "R&D Committee Review of Research as the Only Oversight Committee". R&D Committee Review of human subjects' protocols overseen by the VA CIRB will follow the requirements for R&DC review of protocols overseen by a subcommittee.

iii. For protocols which underwent a major change in scope or funding, the subcommittees or Research Service shall send the protocol to the R&DC for review.

iv. The Research Service will document the review and tracking of submissions of all research projects to determine the nature of the research and will assign review to the appropriate subcommittee of record. This tracking process will identify all reviews required for initial and (if applicable) continuing review submissions. All subcommittee and any applicable component reviews (i.e. Radiation Safety, administration, P&T,, legal, etc.) except Privacy Officer (PO) and Information System Security Officer (ISSO) will occur prior to submission to the R&DC for their review and approval. Protocols requiring and lacking either PO or ISSO review, or both may be submitted to the R&DC for review while PO and/or ISSO reviews are pending. All required reviews will be documented on a checklist developed by the Research Service (R&DC Checklist) and verified by the AO, ACOS, and HRPP manager.

v. Subcommittee chairs and/or committee members per VHA Handbooks, Directives and Research Service SOPs may determine if a research project can be expedited or deemed exempt from IRB or other subcommittee review.

B. R&DC Review Components Include the following for all protocols reviewed.

Additional components will be reviewed for protocols for which the research is overseen by a subcommittee, by an external IRB, or when the R&D Committee is the only oversight committee (as described below):

- Approval by each of the appropriate subcommittees
- The R&DC will also review other protocols for adequate findings/progress if requested by the responsible subcommittee, or if the study had lapsed approval prior to its renewal.
- Adequate resources (space, funding, etc.)
- Appropriate training, credentialing and scope of practice with proper VANCHCS privileges for all research staff
- Valid VA appointments (Paid or WOC) for all research staff
- Required MOUs, service agreements, legal agreements and CRADAs

a. Appropriateness of the work receiving R&D approval – whether the work proposed is VA engaged (conducted by VA personnel, on VA space, using VA resources, etc.)

b. Whether the proposed work is intended to help improve Veteran health

C. R&D Committee Review of Research Overseen by a Subcommittee

1. The R&D Committee may approve a protocol contingent on the protocol being approved by one or more subcommittees. The R&D Committee must ensure the adequacy of each subcommittee's review procedures, including reviewing and approving all subcommittee SOPs. Final approval may only be given after the R&D Committee receives documentation from all

applicable subcommittees of their review and non-contingent approval. Final approval can be provided by a designated reviewer if there were no major changes made by the subcommittee(s). The designated reviewer must have sufficient documentation from the subcommittee(s) to make a determination about any changes requested. This final approval must be reported to the full R&D Committee at its next convened meeting and noted in the minutes.

2. When the R&D Committee relies on the initial review of the subcommittee, the R&D Committee must receive notice from the subcommittee that the research protocol has been approved and a brief written summary of the research to be conducted. Typically, the drafting of the brief summary of the research to be conducted would be the responsibility of a member of the research team and would be included on the project data sheet or equivalent. The R&D Committee may require specific changes or modifications that would require subcommittee re-review.
3. The R&D Committee may disapprove a study even if approved by all subcommittees. The disapproval may be based on such issues as inadequate qualifications of the investigator(s); insufficient relevance to the VA's mission; the presence of inadequate resources to conduct the study; the poor design of the study; concerns related to the protection of human subjects; the welfare of animals used in the research, safety to personnel, the environment, or others; unresolved conflicts of interest that may be detrimental to the research or the facility; or other serious concerns as defined by the R&D Committee.
4. The R&D Committee does not need to approve continuing reviews and amendments but should be provided sufficient documentation in the subcommittee minutes that are provided to the R&D Committee.

D. R&D Committee Review of Research Overseen by an External IRB.

1. In order for an external IRB to serve as the IRB of record for VANCHCS, the external IRB must be listed on VANCHCS's Federalwide Assurance and there must be a MOU in place between VANCHCS and the institution at which the external IRB is based.
2. Investigators who wish to use an external IRB must submit a draft version of the external IRB's review documents to include the protocol, consent form, authorization, and any questionnaires and recruitment documents to the Research Service for administrative pre-review to identify, and if found, resolve any violations of VHA or local policy.
3. The R&D Committee must determine, and specifically document, its determination that the research;
   - Supports the VA mission and is relevant to the care of Veterans
   - Is Scientifically meritorious
   - Ensures the security of VA Data, and storage of data and specimens in accordance with all applicable requirements (see VHA Directive 1605.01 and VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program, dated March 10, 2015).
4. During a convened meeting, the R&D Committee must then vote to approve, approve with contingencies, or not approve the research to be conducted at the facility unless the research

can be approved by the designated review process. NOTE: The full protocol must be available for review by the R&D Committee.

5. The R&D Committee does not need to approve continuing reviews and amendments but should be provided sufficient documentation in the committee minutes that are provided to the R&D Committee.

D. R&D Committee Review of Research as the Only Oversight Committee.

1. Initial Review

- The R&D Committee may use a primary reviewer system or may have one or more members of the R&D Committee review the protocol. The protocol and all applicable documents must be available for all members to review.
- A quorum must be present during the review and approval of the study unless a designated review is used. If the required number of voting members is not present at any point during a meeting, a quorum must be restored before any discussion of, or action on, issues requiring a vote.
- For protocols that require modification to obtain approval, the R&D Committee must communicate their action to the VA investigator. Minor changes (such as spelling and grammar corrections, or other details that do not materially affect risks to subjects, research personnel, or other stakeholders) or as determined by majority vote of R&DC members, may be reviewed and approved by the Chair or a designated voting member of the R&D Committee and given final designated approval of the protocol. The final approval must be noted in the minutes of the next R&D Committee when reported to the full R&D Committee at its next convened meeting.
- At approval, the R&D Committee must set the time frame for continuing review. The time frame may not exceed 365 days. For designated approval, the date of approval is the date of final approval by the designated reviewer once all changes have been made.
- For protocols approved or disapproved by the R&D Committee, a written notification is sent to the ACOS/R&D. The ACOS/R&D notifies investigators, in writing, when a research project can be initiated, and the approval period for the project.

2. Continuing Review.

- Information that must be received by the committee from the PI for continuing review includes:
  - Scientific progress of the research
  - Budget requirement changes
  - Changes in requirements for space, personnel, equipment and supplies
  - Summary and impact of any unanticipated problems.
  - Any issues of serious non-compliance with applicable policies, including privacy and security that have occurred since last approval.
- Once the R&D Committee approves the protocol's continuation written notification is sent to the PI in the form of an approval letter signed by the R&D Committee Chair/designee and the ACOS/R&D.

3. Review of Amendments

Amendments to approved research must be submitted to the R&D Committee for approval.

E. Designated Review

The following activities may be approved by the Chair, R&D Committee or a voting member designated by the Chair:

- Minor changes to a protocol required by the R&D Committee, following full board review.
- Final approval for protocols approved contingent on the full approval of a subcommittee if the subcommittee had not required major changes (see above) to the protocol since the R&D Committee conducted its review.
- Final approval for protocols approved contingent upon completion of the PO and the ISSO review.
- Exempt human subject research protocols and protocols approved by the expedited review by the IRB.
- Single patient expanded access protocols approved by the IRB Chair or another appropriate IRB voting member
- Protocols that do not involve human subjects, biosafety level (BSL-3) or higher containment, use of select agents or non-exempt quantities of select toxins, United States Department of Agriculture (USDA)-regulated animal species, or any animal research involving more than momentary pain or distress to animals.

G. Other R&D Committee Reviews:

The R&DC may also review, as needed, applications for special initiatives (equipment and space requests) or reviews required by other VHA handbooks, which may include, but not be limited to, the following: a) new non-clinical Ph.D. applicants for merit review eligibility b) applicants for the Career Scientist program, c) Endorsement of applicants for the Career Development Program, and d) endorsement of specific projects or awards offered by the Office of Research & Development.

XIV. COLLABORATIVE RESEARCH (see definition below on page 25)

1. Approval of Research. Each institution is responsible for safeguarding the rights and welfare of human subjects, ensuring the welfare of animals, complying with all applicable biosafety and biosecurity requirements and for providing oversight of the research activities conducted at that institution. VA R&D Committee must ensure it only approves VA research activities in a collaborative study.

- Each collaborating institution engaged in the research must obtain approval from the applicable research review committees such as the IRB or IACUC. Each institution must hold a Federalwide Assurance (FWA) if the research is non-exempt human subjects research or a Public Health Service Assurance when conducting research involving animals (see VHA Handbook 1058.03).
- For each individual research study, VA investigators must submit a protocol and other relevant or required documentation to the VANCHCS research review committees and subcommittees such as the IRB, the IACUC, the SRS (as appropriate) and the R&D Committee.

- Each collaborating institution is responsible for safeguarding the rights and welfare of human subjects and providing oversight of the research activities conducted by that institution.
- For human subject's research, VA investigators must submit a protocol or other documentation to their VA IRB of Record that clearly delineates which research activities will be conducted as the VA portion of the overall Collaborative Research study (e.g., by VA investigators on VA time or VA property).
- Each institution engaged in the Collaborative Research must use the informed consent document and HIPAA authorization required by its respective institutional policies for subjects recruited from that institution, or procedures requiring participation of the subjects at that institution. The informed consent document may contain information on the project as a whole as long as the document clearly describes which procedures will be performed under VA's auspices and which will be performed under a non-VA institution's auspice. (a) The VA informed consent document must clearly state when procedures conducted at other non-VA institutions are part of the VA's portion of the study. (b) The informed consent document and HIPAA authorization (for the VA portion of the collaborative study) must not contain inconsistent provisions.

2. Research Data. The protocol, study application, and/or required study application appendices and/or attachments such as a data use agreement must describe the data (identifiable or de-identified if from human subjects or sensitive or non-sensitive if animal or other research) to be disclosed to collaborators, the entity(ies) to which the data are to be disclosed, the method of how the data are to be transmitted, and the person who will own or have responsibility for the disclosed copies of the data. This includes data developed directly from the research including the analytic data and the aggregated data. It is local policy that a data use agreement (DUA) will be required whenever VA data (identifiable or de-identified if from human subjects or sensitive or non-sensitive if animal or other research) is transmitted outside of VA or for VA data developed during VA research outside the VA in facilities covered by a full or partial off-site waiver. DUA are expected to contain all the elements included on templates included in VHA Handbook 1080.01, "Data Use Agreements". *Note: If a CRADA is executed for a research study where the scope of work specifically describes the data to be disclosed to collaborators, the entity(ies) to which the data are to be disclosed, the method of how the data are to be transmitted, and the person who will own or have responsibility for the disclosed copies of the data and the disposition of the data, then a DUA is not required.*

- Each VA facility must retain a complete record of all data obtained during the VA portion of the research in accordance with privacy requirements, the Federal Records Act, and VHA Record Control Schedule 10-1.
- All disclosures and data transmission must meet privacy and security requirements per VHA Directive 1605.01 and VA Handbook 6500.

3. Biospecimens. The protocol, study application, and/or required study application appendices and/or attachments must describe the applicable collection, use, transfer, and disposition of biospecimens obtained or collected. A Material Transfer Agreement (MTA) must be used to transfer biospecimens from VA unless the biospecimens transfer is addressed in another agreement executed between VA and the receiving institution or party, such as a CRADA, subaward, or MOU. It is local policy that an MTA (or

CRADA, subaward or MOU) is required for any transfer of biospecimens outside the VA and for all biospecimens collected, accessed, or analyzed as part of VA research performed off-site through a full or partial off-site waiver. Such MTA are expected to include all the elements present in MTA templates available at the website https://www.research.va.gov/programs/tech_tranfer/model_agreements/ under the heading "Data Collection Agreement". **NOTE:** *If a CRADA is executed for a research study where the scope of work specifically describes analysis, retention, and disposition of biospecimens by a central laboratory, then a MTA is not required.* Note: Per April 19, 2019 update from the DUSH for Discovery, Education, and Affiliate Networks, implementation of the requirement for a MTA for transfer of biospecimens from VA for collaborative research unless the biospecimens transfer is addressed in another agreement executed between VA and the receiving institution or party, such as a CRADA, subaward, or MOU will be delayed. Implementation of the above noted requirement for MTA will occur when notification to do so is received from the Office of Research Protections, Policy, and Education and/or the DUSH for Discovery, Education and Affiliate Networks. All other provisions of this SOP (except as indicated) will be implemented at the time of signing by the R&DC Chair and the ACOS/Research. The delay in implementing the requirement for MTA does not alter the requirement for a CRADA for collaborative research in which the VA is proposed to accept, retain and use funds, personnel, services, facilities, intellectual property, equipment or other resources from a Federal or non-Federal partner as described in VHA Directive 1206.

XV. PARTICIPATION OF NON-VETERANS AS RESEARCH SUBJECTS

- Non-Veterans may be entered into a VA-approved research study that involves VA outpatient or VA hospital treatment, but only when there are insufficient Veteran patients suitable for the study (see 38 CFR 17.45, 17.92). The investigator must justify including non-Veterans, and the R&D Committee must review the justification and provide specific approval for recruitment of non-Veterans.
- **Outpatient Care for Research Purposes**. Any person who is a bona fide research volunteer may be furnished outpatient treatment when the treatment to be rendered is part of an approved VA research study and there are insufficient Veteran patients suitable for the study (see 38 CFR 17.92).
- **Hospital Care for Research Purposes**. Any person who is a bona fide research volunteer may be admitted to a VA hospital when the treatment to be rendered is part of an of an approved VA research study and there are insufficient Veteran patients suitable for the study (see 38 CFR 17.45). When reviewing requests for hospital care for research purposes, the R&DC will be mindful of the very limited inpatient capacity of VANCHCS and the high cost to the facility that is incurred when the facility's limited inpatient capacity requires Veteran patients to receive inpatient treatment in the private sector.
    - Non-Veterans may be recruited for studies that will generally benefit Veterans and their well-being but would not include Veterans as subjects. Examples include surveys of VA providers, studies involving Veterans' family members, or studies including active duty military personnel. Although active duty military personnel are not considered Veterans, they should be included in VA studies whenever appropriate.

- In addition to the non-Veterans referenced above, active duty military personnel may be entered into VA research conducted jointly by VA and DoD or within DoD facilities.
- All VA regulations and policies related to Veterans as research subjects apply to non-Veterans entered into VA research.
- Non-Veterans may not be entered into VA studies simply because a non-Veteran population is easily accessible to the investigator.
- Investigators must follow VHA Handbook 1605.04, Notice of Privacy Practices, to provide notice for privacy practices and acknowledgement for any non-Veteran enrolled in the approved protocol. Investigators will be notified of this fact when notified of the approval to enroll non-Veterans in their study.

XVI. R&D COMMITTEE RECORDS

A. Adequate documentation of all of the activities of the R&DC must be maintained, including, but not limited to, the following:

i. Minutes of the R&DC and its subcommittees to include attachments of all documentation provided to committee members.

a. The R&DC minutes are completed by the R&DC Coordinator or designated research staff. In general, the minutes reflect key business items conducted at the R&DC meeting and include a summary of any discussions, deliberations, modifications required, actions taken and the votes underlying those actions. The minutes must reflect deliberations of oversight functions; items needing further review or action and approval of all VA research.

b. Minutes of the meeting are reviewed by the members and reviewed and signed by the Chairperson, Executive Secretary (ACOS/R), Chief of Staff, and the Medical Center Director.

c. Copies of draft minutes, together with any comments from the Director, will be distributed as part of the agenda packet for review and approval at the next schedule meeting of the R&DC.

d. Minutes and attachments shall be maintained by the R&DC Coordinator and made available to appropriate officials upon request.

ii. R&DC Correspondence to PIs regarding research projects are kept within appropriate research project file located in Research Services and attached to R&DC minutes when appropriate.

iii. The R&DC Coordinator is responsible for maintaining updated membership/alternate membership rosters for the R&DC as well as its subcommittees. Rosters will include at a minimum the name, title, and representative capacity of each member.

iv. R&DC members are provided with a copy of this standard operating procedure at the time they join the R&DC and notified of any updates to this SOP. The ACOS/R, R&D leadership staff, the RCO, R&DC Chairperson/Members and others, as needed, work together to write and maintain this SOP and coordinate changes with SRS, IRB and IACUC SOPs as needed. The SOP is reviewed and modified as needed to ensure compliance with federal and institutional regulations and policies.

v. The Research Service will utilize and maintain a computerized tracking system to store information regarding which documents have been received, when they were reviewed, and the results of that review. Additionally, the computerized tracking system will track when changes were received and

approved, and the date of continuing review. The computerized tracking system also tracks R&DC membership and can assist the R&DC coordinator and research staff in generating meeting minutes and correspondence. The Research Service also uses the VA enterprise project management information system (ePROMISE), and may utilize other software as needed to help track and process projects and communications.

vi. Research records are accessible to Research Service staff, R&DC Chairperson and members. Research investigators shall be provided reasonable access to files related to their research. Other authorized individuals, such as officials of Federal and state regulatory agencies, including the Office of Research Oversight (ORO), the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and the VA Office of the Inspector General, will have access to Research Service records for inspection and copying upon determination of appropriateness and necessity at reasonable times and in a reasonable manner.

vii. All research records are kept according to the VHArecords control schedule (RCS) 10-1 and per SOP on Record Retention. In cases where the sponsor or the Food and Drug Administration (FDA) require longer retention, the records will be retained for the longest of the required timelines. The Research Service maintains all records collected over the course of a study.

XVII. R&D COMMITTEE - SUBCOMMITTEES/KEY FUNCTIONS/COMPONENT REVIEWS

A. SUBCOMMITTEES

i. Institutional Review Board (IRB) Subcommittee: The R&DC has charged the VANCHCS IRB with the oversight of all research activities involving the use of human subjects (see definition page 26). The VANCHCS IRB shall perform all functions required under 38 CFR 16 (Common Rule), 45 CFR 46 Subparts A through D, 21 CFR 50 and 56 (where applicable), and VA rules and policies set forth in writing in VHA Directive 1200.05 for reviewing and approving human research conducted under the auspices of the Institution's Federal- wide Assurance (FWA) and per the VANCHCS IRB SOP.

ii. Subcommittee for Research Safety and Security (SRS): The R&DC has charged the VANCHCS SRS with ensuring all research activities involving biological, chemical, physical, radiation or any other hazards for compliance with all applicable regulations, policies, and guidelines.

a. The SRS is also charged by the R&DC with the responsibility to maintain the security of the research program in a manner that is consistent with VA policies, Federal statutes and regulations from Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the Nuclear Regulatory Commission (NRC), etc., and any applicable State and local requirements. When required, the SRS will ensure measures are in place to control access to VA research laboratory areas housing select agents, toxins, and other hazardous agents. The authorities, responsibilities, and procedures of all SRS functions are described in the SRS SOP and Laboratory Safety Manual.

b. For all VA engaged research that does not involve human subjects, but where the proposed work comprise a safety issue, for example, those that require wet bench laboratories, the SRS will also act as the subcommittee of record.

iii. Institutional Animal Care and Use Committee (IACUC) (MOU with University of California Davis (UCD) as the IACUC of Record): Through an approved MOU, the R&DC oversees and has charged the

University of California Davis (UCD) IACUC with ensuring compliance with animal research regulations for VANCHCS. Processes are documented in the UCD –VA MOU, UCD IACUC SOPs and the UCD Animal Care and Use Program. An IACUC member will also be a member of the SRS and the R&DC.

a. VANCHCS R&DC is required to ensure the UCD IACUC is comprised of investigators, a veterinarian, VMU staff, and a representative from the public. The UCD IACUC SOP contains the procedures and principles by which the UCD IACUC abides in the review and conduct of research involving animal research subjects. The IACUC is responsible for coordinating training, compliance and occupational health programs. It may suspend activity involving animals which violates approved animal welfare regulations. The IACUC consults with researchers on preparing animal studies. The VMU from UCD works closely with the IACUC and is accredited by AAALAC.

b. The UCD IACUC and VANCHCS will maintain files and documents that pertain to VANCHCS IACUC-approved animal studies, including minutes, approved protocols, approved amendments, semiannual reviews and relevant communications with investigators. Access to these documents will be made available to VANCHCS Research Service through the VANCHCS representative to the IACUC who has access, to the Secure University of California, Davis, IACUC Business Administration Electronic System, IACUC Office Program Area and Function site.

iv. Institutional Biosafety Committee (IBC) (MOU with UCD as the IBC of Record): Through an approved MOU, the R&DC oversees and has charged the UCD IBC with ensuring compliance, safety, and adherence to National Institutes of Health (NIH) "NIH Guidelines for Research involving Recombinant or Synthetic Nucleic Acid Molecules" (NIH Guidelines). All issues concerning the biological safety of research involving rDNA are outlined in the MOU with UCD for the IBC. Processes are identified in the SRS SOP, the UCD–VA MOU, and UCD IBC Policies. An IBC member will also be a member of the SRS and the R&DC.

a. The UCD IBC and VANCHCS will maintain files and documents that pertain to VANCHCS IBC-approved proposals, including minutes, approved proposals, recommendations, and relevant communications with investigators. Accesses to these documents are made available to the VANCHCS representative to the IBC. Copies of IBC minutes and file documentation of current IBC-approved VA proposals are maintained in the VANCHCS Research Service as outlined in the SRSSOP.

v. The UCD IBC VANCHCS MOU's scope only pertains to studies with rDNA proposals. The PI will be contacted by the UCD IBC with the results of their review and VANCHCS must track these findings through the R&DC. THE VANCHCS R&DC will ensure that VANCHCS researchers using rDNA will conform to the UCD IBC recommendations as well as all other regulatory processes of the VA SRS and R&DC. VANCHCS maintains authority to approve, disapprove or require modifications of all research conducted at VANCHCS, but will not approve an rDNA protocol that the UCD IBC has disapproved.

vi. VA Central IRB (CIRB)

a. The purpose of VA CIRB is to enhance the quality of human research protection in multi-site human research projects by performing appropriate ethical and scientific review while ensuring local issues are addressed and enhancing the efficiency of these reviews across participating sites. Typically, VA CIRB provides human subjects research oversight of VA research funded by ORD. However, the VA CIRB may agree to provide human subjects oversight over multi-site studies funded

from other sources and VANCHCS is able to delegate human research protection to the VA CIRB in these instances.

b. VANCHCS must ensure that the VA CIRB is added to its Federal-wide Assurance (FWA) and must sign a Memorandum of Understanding (MOU) with the VHA Central Office (VHACO) HRPP. The MOU must clearly delineate the respective roles and responsibilities of each entity. The local VA has ultimate responsibility for its HRPP. In addition, any affiliated Nonprofit Research and Education Corporation (NPC) for a VA site that has entered into an MOU with the VHACO HRPP, should also sign the MOU and update its FWA to add the VA CIRB as an IRB of Record.

c. CIRB studies will undergo initial reviews locally through the R&DC utilizing the same applicable subcommittee and component review process as all other VANCHCS studies. Initial review will occur when the final approval

letter and documents have been received from the CIRB. The CIRB must show continuing review and approval before the expiration date.

d. Application forms and other information concerning the operations of the VA CIRB can be found on the website (http://www.research.va.gov/vacentralirb/) under the "Important Links" box.

B. SUBCOMMITTEE MEMBERSHIP

i. The members of the subcommittees (including alternates and *ex officio*, non-voting members) can be nominated by any of the following: Research Service Staff; PIs; facility leadership; R&DC and subcommittee Chairs, facility staff. Memberships of the subcommittees are reviewed by the R&DC, and appointed by the Medical Center Director.

C. SUBCOMMITTEE OF RECORD

i. All studies will be assigned a subcommittee of record which is responsible for the following protocol reviews:

- **a.** Review of research protocol to ensure scientific merit
- **b.** VA engagement
- **c.** Maintenance of high standards of protocol review
- **d.** Relevance to the mission of the VA

ii. The subcommittee of record is designated as follows:

- **a.** IRB Committee – All Human Studies
- **b.** SRS Committee – All Non-Human Studies

D. SUBCOMMITTEE REVIEWS AND APPROVALS OF PROJECTS

i. Subcommittee reviews and approvals of projects must ensure the following when appropriate:

- **a.** Protection of human subjects (including privacy and confidentiality), and the implementation of measures to minimize risk to research subjects
- **b.** Welfare and appropriate use of animals in research to include adequate resources
- **c.** Safety of personnel engaged in research to include adequate resources and training or research personnel
- **d.** Security of research laboratories where hazardous agents are stored or utilized
- **e.** Security of VA data and VA sensitive information
- **f.** Appropriate use of VA resources and minimization of liability risk to VA.

E. RECORDS AND DOCUMENTATION

i. Each subcommittee must document its discussions as well as any actions taken in the meeting minutes which are reported to and approved by the R&DC. Documentation of Subcommittee and Component Reviews will be completed by Research Service. All subcommittee records must be maintained in accordance with the VHA records control schedule (RCS) 10-1.

F. COMPONENT REVIEWS

i. Radiation/MRI/fMRI Review: The VANCHCS Radiation Safety Committee is responsible for ensuring a process for review of Radiation/MRI/fMRI Safety as it relates to any project submission. Refer to the VANCHCS MRI SOP for details. The protocol submission packet will guide PIs as to completion necessary information. This required review must be completed before projects may be approved.

ii. Pharmacy & Therapeutics (P&T) Review: Human studies involving receipt, storage, and use of pharmaceuticals require P&T review. This process is defined in Pharmacy SOPs, and described in the protocol submission process. The IRB must ensure protocols requiring P&T review have P&T approval prior to initial IRB approval.

iii. Privacy Office/Information Security Office Review: Human Research protocols (including exempt projects) require the review of the Privacy Office (PO) and Information System Security Office (ISO) to ensure the research complies with all applicable local, VA, and other Federal requirements for privacy, confidentiality, and information security. The process for the PO review is described in the local Privacy Office Review of Research Projects SOP.

iv. Public Affairs Review: Protocols using recruitment materials (i.e., flyers, advertisement, internet posting, etc.) require the review of the Public Affairs Office.

XVIII. CONFLICT OF INTEREST

A. R&DC members and VA investigators must comply with VA requirements on financial conflicts of interest in research. The R&DC will follow guidance as outlined in Directive 1200.01 and the VANCHCS SOP for Conflict of Interest. R&DC Committee members must self-declare any conflict of interest and recuse themselves from voting when a conflict of interest exists. An R&DC Member Conflict of Interest Declaration will be completed annually by all members of the R&DC.

XIX. NON-COMPLIANCE AND SYSTEMIC DEFICIENCIES

A. Non-compliance

i. The R&DC will initiate a review if there is any allegation or other evidence that there has been a violation of safety policies/procedures or compliance issues. The R&DC has the authority to examine all records that involve research. The R&DC may also choose to review the working environment of any investigator at any time and without notice. The R&DC will generally delegate investigative responsibility to an R&DC subcommittee and the RCO. The R&DC will consider the evidence and will determine by vote if the non-compliance is confirmed.

ii. Systemic Deficiencies: VA personnel, including WOC and IPA appointees, must ensure written notification to the VA facility's R&DC within 5 business days after becoming aware of any apparent

systemic deficiency that has a reasonable likelihood of substantially compromising the facility's research protection programs, including persistent failure by any subcommittee of the R&DC to adhere to the requirements governing VA research. When notified of such deficiencies the R&DC:

a. Must review any notification under paragraph **ii** above at its earliest practicable convened meeting, not to exceed 30 business days after the date of notification.

b. May hold unscheduled meetings in response to emergent issues in accordance with VHA Directive 1200.01.

c. Must determine whether the notification involves an actual systemic deficiency that could substantially compromise the VA facility's research protection programs, and if so:

i) The R&DC must determine what remedial actions, if any, are warranted to ensure effective research protections;

ii) The R&DC must notify the VA facility Director and the ACOS/R within 5 business days after the determination; and

iii) The VA facility Director must report the determination and the resultant remedial actions to ORO within 5 business days after receiving the notification.

Title 38 CFR 16

REFERENCES

VHA policy concerning Research Financial Conflict of Interest Statement

VHA policies concerning Credentialing of Health Care Professionals

VHA Handbook 1058.01	Research Compliance Reporting Requirements
VHA Handbook 1058.2	Research Misconduct
VHA Handbook 1058.03	Assurance of Protection for Human Subjects in Research
VHA Handbook 1058.04	Debarments and Suspensions Based on Research Impropriety in VA Research
VHA Directive 1200.01	Research and Development Committee
VHA Directive 1200.05	Requirements for the Protection of Human Subjects in Research
VHA Handbook 1200.06	Control of Hazardous Agents in VA Research Laboratories
VHA Handbook 1200.07	Use of Animals in Research
VHA Handbook 1200.08	Safety of Personnel Engaged in Research
VHA Directive 1605.01	Privacy and Release of Information
VA Handbook 6500	Information Security Program
VHA Directive 1206	Use of Cooperative Research and Development Agreement (CRADA)
VHA Directive 1200 VHA	Research and Development Program

VHA Directive 1058	Office of Research Oversight
VA Directive 6500	Information Security Program
VHA Directive 2007-040	Appointment of Facility Information Security Officer (ISO) and Privacy Officer to the Institutional Review Board (IRB) or the Research and Development (R&D) Committee

DEFINITIONS/ACRONYMS

Adverse Event (AE). An AE is any untoward physical or psychological occurrence in a subject participating in research. An AE can be any unfavorable and unintended event, including an abnormal laboratory finding, symptom, or disease associated with the research or the use of a medical investigational test article. An AE does not necessarily have to have a causal relationship with the research (see subpars.3w and 3ll and VHA Handbook 1058.01).

Administrative Officer for Research Service (AO/R). The AO/R is the individual responsible for the administrative functions of the research program.

Associate Chief of Staff for Research Service (ACOS/R). The ACOS/R is the individual that is responsible for the day-to-day management of the research program. ***NOTE:*** *Although the Director or Chief Executive Officer (CEO) of each health care facility is responsible for the R&D program of that institution, advised and assisted by an R&DC, all facilities with an active R&D program must have an official responsible for management of the program.*

Affiliated Institution. An affiliated institution is an academic institution that has a relationship with a VA medical center documented by a Memorandum of Affiliation in conformance with VA regulations (also referred to as "academic affiliate"). In addition, special purpose affiliations documented by a Memorandum of Understanding (MOU) approved by the Chief Research and Development Officer (CRADO) for VHA may be developed in R&D areas such as health services or rehabilitation research and development.

Classified Research. Classified research is research that is considered restricted or secret by the Federal government, sponsor, or any third party. For example, research for the Federal government that is considered sensitive or would affect national security.

Collaborative Research. Collaborative Research is a research collaboration involving investigators from VA and other institutions, with VA investigators having a substantive role in the design, conduct, and/or analysis of the research.

Common Rule. The phrase "common rule" means the Federal Policy for the Protection of Human Subjects. VA codified it at 38 CFR Part 16.

Cooperative Research and Development Agreement. A Cooperative Research and Development Agreement (CRADA) is an agreement established pursuant to 15 U.S.C. 3710a between VA and one or more non-Federal parties under which VA may accept, retain, and use funds, personnel, services, facilities, intellectual property,

equipment or other resources from the other party, as well as provide personnel, services, facilities, intellectual property, equipment or other resources, excluding funding, toward the conduct of specified research and development that is consistent with VA's mission. (See VHA Directive 1206, Use of a Cooperative Research and Development Agreement (CRADA), dated June 19, 2018).

Cooperative Study. A VA cooperative study is a project or program of research or development conducted at two or more VA health care facilities using common protocol so that data obtained at all participating facilities can be treated as though from a single source.

Co-Principal Investigator (Co-PI). A Co-PI is one of two or more principal investigators who share equality in the accountability for a study. A Co-PI must meet the same qualifications as a PI.

VA Engaged Research. VA Research is research that is approved by the R&DC and conducted by VA investigators including PIs, Co-PIs, and Site Investigators, (serving on compensated, WOC, or IPA appointments) while on VA time, utilizing VA resources, or on VA property including space leased to, and used by, VA. The research may be funded by VA, by other sponsors, or be unfunded. (VHA Handbook 1200.01).

***Ex officio* member.** An ex-officio member is the individual who serves as a member of a committee by virtue of that individual's position. An ex-officio member is a non-voting member on the R&DC.

FWA/Assurance: Assurance (Assurance of Compliance). For human research, an Assurance is a written commitment to protect human subjects participating in research and to comply with the requirements of 38 CFR Part 16. Assurances are reviewed and approved by the HHS Office for Human Research Protections (OHRP) and various other departments and agencies under the Federal Policy (Common Rule) for the Protection of Human Subjects (56 FR 28001, June 18, 1991) (see VHA Handbook 1058.03).

Generalizable Knowledge. For purposes of this manual, generalizable knowledge is information that expands the knowledge base of a scientific discipline or other scholarly field of study. Systematic investigations designed to develop or contribute to generalizable knowledge constitute research. Thus, systematic investigations designed to produce information to expand the knowledge base of a scientific discipline or other scholarly field of study constitutes research.

HRPP Administrator: Human Research Protection Program (HRPP) A HRPP is a comprehensive system to ensure the protection of human subjects participating in research. At the VA facility, the HRPP consists of a variety of individuals and committees including, but not limited to: the VA facility Director, ACOS/R, AO/R, RCO, HRPP point of contact; R&DC, IRB, other committees or subcommittees addressing human subject's protection, investigators, IRB staff, research staff, health and safety staff and research pharmacy staff. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research. The facility Director is responsible for overseeing the creation and implementation of an HRPP for research involving human subjects or human biological specimens.

Human Subject: A human subject is a living individual about whom an investigator (whether professional or student) conducts research, and:

(1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
NOTE: *Individuals who receive test articles or who serve as controls in clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are also considered human subjects.*

Institutional Animal Care and Use Committee (IACUC). IACUC is the local committee charged with ensuring compliance with animal research regulations and guidelines. At VA medical centers, the IACUC is a subcommittee of the R&DC and can be served by a local affiliate (refer to VHA Handbook 1200.7). For the VANCHCS this function is served by a local affiliate.

Institutional Review Board (IRB). An IRB is a board, committee, or other group formally designated by an institution to review, approve, require modification, disapprove, and conduct continuing oversight of human subject research in accordance with 38 CFR part 16 and other applicable regulations.

Research Involving Recombinant (DNA). The R&D program must comply with the National Institutes of Health (NIH) Guidelines for Research Involving DNA Molecules.

Investigational Device. As defined by the FDA, an investigational device is a device that is the object of an investigation (21 CFR 812.3(g).
Investigational Drug. According to VHA Handbook 1108.04, an investigational drug is a chemical or biological drug that is used in a clinical investigation.

Memorandum of Understanding (MOU). A MOU is a written agreement entered into by and between two or more parties to set forth the terms, conditions, and understandings of the parties with respect to a specific activity. For example, an MOU may be developed to delineate each party's responsibilities, as allowable by law, in collaborations between two or more Federal agencies, or between a Federal agency and a private entity such as a medical center and its affiliated nonprofit research corporation.

Non-Research Operations Activities. Activities that are not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field) do not constitute research. Thus, a VHA operations activity does not constitute research if both of the following criteria are satisfied:

(1) The activity is designed and implemented for internal VA purposes (i.e., its findings are intended to be used by and within VA or by entities responsible for overseeing VA, such as Congress or the Office of Management and Budget); and

(2) The activity is not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field).

Office of Research and Development (ORD). Within VHA Central Office, ORD is the office responsible for the overall policy, planning, coordination, and direction of VA research activities.

Office of Research Oversight (ORO). ORO serves as the primary VHA office in advising the Under Secretary for Health on all matters of compliance and assurance regarding human subject protections, animal welfare, research safety and security, research information protection, and research misconduct. ***NOTE:*** *ORD and ORO are two separate offices within VHA.*

Off-Site Research. Off-site research is research performed at sites other than VA medical centers, other VA space, or VA leased space. Policies regarding off-site research are clarified in VHA Handbook 1200.16.

Research Compliance Officer (RCO): Reports directly to the VANCHCS Director and is responsible for developing and implementing a research compliance program. The RCO is an individual whose primary responsibility is to review research projects relative to requirements for the protection of human subjects, laboratory animal welfare, research safety, research laboratory security, research information protection, and other areas under the jurisdiction of ORO.

Research Space. Research space refers to all types of space where research is conducted including dry lab space (for programs more dependent on generation, collection and analysis of clinical data), wet lab space (for biomedical experimentation) and any combination or customization of wet or dry lab space to meet the special needs of VANCHCS investigators.

Operations Activities Constituting Research. An operations activity may or may not constitute research, depending on whether the activity is designed to produce information to expand the knowledge base of a scientific discipline (or other scholarly field of study).

(1) An operations activity is designed to develop or contribute to generalizable knowledge if the conceptualization, plan, or implementation of the activity is supplemented or modified in order to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study)

(2) It is important to distinguish data collection for non-research operations purposes from subsequent use of the collected data for research purposes.

(3) An activity that was initially designed as a non-research operations activity subsequently becomes research if it is supplemented or modified in order to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study). In such situations, the modifications and additions to the original activity constitute research.

(4) The fact that a particular activity is mandated by Congress or another oversight body or authority has no bearing on whether or not the activity meets the definition of research.

Research Safety Program. The R&D program maintains a research safety program consistent with policies, statutes, and regulations issued by the Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC), Centers for Disease Control and Prevention (CDC), and NIH. The R&D program supports only those studies with the highest standards of protecting personnel against biohazards, chemical hazards, and physical hazards in research settings including VA research laboratories.

Research Security Program. The research security program addresses a number of areas including: Privacy, confidentiality, and security of all VA sensitive information and compliance with all applicable Federal statutes and regulations related to privacy and security including: the Privacy Act of 1974; the Health Insurance Portability and Accountability Act; 38 U.S.C. 5701, 5705, and 7332; the Federal Information Security Management Act of 2002; VA Handbook 6500; VA Handbook 6502; and all other VHA privacy, confidentiality and security policies. ***NOTE:*** *HHS has issued regulations, the Standards for Privacy of Individually Identifiable Health Information, codified at 45 CFR parts 160 and 164.*

Research Information Security. Research information security is the protection of information and information systems that includes management, operational, and technical procedures for maintaining the confidentiality, integrity, and availability of research data and information in accordance with the Federal Information Security Management Act of 2002 (FISMA, 44 U.S.C. 3541, et seq.) and VA Directive and Handbook 6500, Information Security Program.

Multi-site Research. If conducting human research studies involving more than one engaged institution, each institution is responsible for safeguarding the rights and welfare of human subjects entered at its site, and for complying with all applicable local, VA, and other Federal requirements.

Research – aspects of protocol performed at other non-VA Sites. If the study requires services not provided by VA, then the R&DC should evaluate the relevance of the protocol to the care of Veterans. If it is relevant then the next step would be to see what safeguards are in place when the services are obtained for clinical care and decide if they are sufficient. When services are purchased, there must be a written agreement for them.

Subcommittee for Research Safety (SRS). The SRS is the local committee charged with ensuring compliance with all applicable regulations, policies, and guidelines pertinent to biological, chemical, physical, and radiation hazards, and with oversight of all research activities involving safety hazards. At VA medical centers, the SRS is a subcommittee of the R&DC.

VA Data or VA Information. VA data or VA information owned or in the possession of, under the control of, or collected by VA or any entity acting for, or on behalf of VA. The data may be identifiable, de-identified, sensitive, or non-sensitive.

VA Investigator. A VA investigator is any individual who conducts research approved by the VA R&DC while acting under a VA appointment on VA time, including full and part-time employees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the IPA of 1970. As a VA investigator, that individual represents the interests of the VA in conducting the VA approved research. In addition, a VA investigator must comply with all applicable VA and VHA regulations and policies.

VA Research. VA research is research conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. The research must be approved by the R&D Committee before it is considered VA research and before it can be initiated.

VA Sensitive Information and Data. VA sensitive data means all VA Data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information and includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, and records about individuals requiring protection under applicable confidentiality provisions (see 38 U.S.C. 5727).

Without Compensation (WOC) Appointment. A WOC is an individual that has been officially appointment by the office of Human Resource Management but does not receive any monetary compensation from VA. This appointment may allow the individual to support the VA research program in various capacities including but not limited to investigator, research coordinator, and administrator while at VA for a defined period oftime. WOCs are subject to laws and regulations pertaining to Government personnel including but not limited to VHA's credentialing and privileging policy

RESCISSION, RECERTIFICATION, AND APPROVAL

Rescission:

R&D Committee SOP

DATED: April 24, 2019

Recertification and Approval- must be at least annually by R&DC

Reviewed and Approved by R&D Committee

SIGNATURE: Paramita Ghosh
Paramita Ghosh, Ph.D., Chairperson

SIGNATURE: Dawn Schwenke
Dawn Schwenke, Ph.D., ACOS/R

Attachment 1: Research and Development Committee Oversight Procedures

I. Procedures: To ensure effective oversight, the R&DC relies on information sources including, but not limited to, activities of the R&DC, quality assurance activities, reports to the committee by the ACOS/R, AO/R, or other research staff members, subcommittee reports, and facility reports or activities. Specific issues and documents to be considered may include:

A. Ongoing Reviews:

- **i.** All Subcommittee minutes
- **ii.** CIRB minutes when applicable
- **iii.** Sub-committee and Component Review Sheets
- **iv.** Compliance reviews and audits
- **v.** Laboratory safety inspection reports
- **vi.** Reports to Office of Research Oversight (ORO)
- **vii.** IACUC inspections

B. Upon review and approval by the R&DC, annual evaluations of the following will be forwarded to the Medical Center Director. Each evaluation will include an assessment of minutes, support staff, budget, space needs, goals, quality improvement activities, and compliance issues. Additional assessments will also include the following:

- **i.** Human Research Protection Program including:
  - **a.** IRB composition or IRB arrangements
  - **b.** Credentialing and training status report
- **ii.** Animal Care and Use Program including:
  - **a.** Inspection reports
  - **b.** IACUC composition
  - **c.** Training
- **iii.** Research Safety and Security Program
  - **a.** Annual reviews/audits
  - **b.** Planned training
  - **c.** Security issues
- **iv.** Institutional Biohazard Committee
  - **a.** Inspection reports
  - **b.** IBC composition
  - **c.** Training
- **v.** Research Space and Renovation:
  - **a.** Findings and impact for research space including regular analysis of program/staff needs with a close interface with Facility-Wide Space Committee.
- **vi.** Information pertaining to all requests for appointments for research. Review is to include the following:
  - **a.** Assurance that information pertaining to all WOC appointments for research has been appropriately justified and the appointments are in compliance with all applicable research, human resources and VA policies.

b. Review of research employees involved in human subject's research to ensure the employees are working within their scopes of practice and their privileges allowed by the facility's by-laws and granted to them by the facility.

vii. An annual quality assurance review of publications assessing the appropriate acknowledgement of VA support and affiliation.

viii. An annual quality assurance review of all Cooperative Research & Development Agreements (CRADAs) and all other research related legal agreements.

ix. An annual review of the R&D Program's resource needs which will include personnel, materials and supplies, space, capital equipment, training and education. This review will consider the information obtained from all the other reviews described above.

II. All oversight evaluations will be conducted by the convened R&DC. The evaluation and recommendation of the R&DC will be documented in the R&DC Minutes and provided to the Medical Center Director.

Attachment 2: Research Appointment Requirements

Anyone working in Research and Development (R&D) at VANCHCS must be a paid VA employee or have a without compensation (WOC) appointment. A VA appointment in another VANCHCS Service other than R&D is acceptable, however additional forms specific to Research Service may be required. Research Personnel should be properly appointed based on an active link to a research protocol.

Credentialing and Privileging of Research Staff
Credentialing is the system by which the facility verifies education and experience of applicable staff. If required, the credentialing process must be fully completed prior to working on approved research projects.

If an applicant's position requires them to use their license, certification or registration to perform their job duties, privileges must be granted in accordance with the facility's Medical Staff Bylaws, Rules and Regulations prior to performing the interventions covered under the privileges to be granted.

A Without Compensation (WOC) Appointment is required for anyone who is not a VANCHCS paid employee and who will have access to or be involved with any of the following.

- Identifiable data or interact with human research participants
- Work on VA property and on VA engaged research
- Be on an Intergovernmental Personnel Agreement (IPA)
- On a contract through another VANCHCS service

A VANCHCS research WOC appointment **is not** required if:

- WOC through another VANCHCS Service has already been granted, this includes medical residents and fellows who have approval to work at VANCHCS

Attachment 3: R&D Committee Communication Procedures

I. Purpose: This procedure addresses written communication to and from the R&DC to the Director, COS, Investigators and Subcommittees.

II. R&DC Correspondence: Records of all communications to and from the R&DC are maintained by the Research Service. The R&DC Chair signs R&DC correspondence as appropriate. Correspondence includes written communications to the Medical Center Director, the Chief of Staff, investigators and committees or subcommittees on behalf of the R&DC. Verification of receipt of critical correspondence is obtained by Research Service/R&DC Coordinator.

III. Subcommittee project actions/approvals: Notification of subcommittee approvals are communicated to the R&DC via the R&DC Checklist. The R&DC requires all component reviews be carefully delineated and signed and dated by R&D leadership. Subcommittee approval letters must be signed by a voting member of the committee and will be attached to the R&DC Checklist. The R&DC Coordinator must not place any research requiring review on the R&DC Agenda without a completed R&DC Checklist.

IV. PI Notification of R&DC Actions: The R&DC must notify the ACOS/R of project approvals, suspensions, etc. Written communication to the ACOS/R will be signed by a voting R&DC member; however most often will be signed by the Chairperson. Investigators shall then be notified in writing by the ACOS/R of any determinations made by the R&DC. For suspensions and terminations/discontinuations, verification of receipt by the PI must be documented.

V. Project Files and Correspondence: Copies of correspondence and verification of receipt, as applicable, are filed in the appropriate research project file kept in the VANCHCS Research Service office. A signed hard copy of the correspondence from the R&DC and the ACOS/R will be mailed to the investigator for their files. Responses to the R&DC should come from the Investigator and may be communicated electronically or by hard copy.

VA NORTHERN CALIFORNIA HEALTH CARE SYSTEM (VANCHCS)

Research and Development Committee (R&DC)

Annual R&DC Member Conflict of Interest Declaration

R&DC members must recuse themselves from the review of proposals or any agenda item for which any conflict of interest may exist. Conflicting interest includes participation in or supervision of the project, a financial interest, a personal relationship, fiduciary relationship, or other situations giving rise to a conflicting interest, as defined in the VANCHCS Standard Operating Procedures, *Identifying, managing, and minimizing individual conflict of interest.*

☐ I am currently involved, and/or have a conflicting interest regarding the following active research protocol(s): (list all protocol numbers) ☐not applicable

_____

_____

_____

_____

Initials

_____ I will inform the R&DC should my involvement with protocol(s) changes or should I discover such a conflict before or during the meeting.

_____ I will leave the room during the discussion, deliberation, or vote on any research protocol or agenda item in which I am involved and/or have another type of conflicting interest.

Name of R&DC Member: _____

Member Signature:_____Date: _____